

Consumer Product Safety Commission

§ 1240.5

50 kG² mm² or less when tested in accordance with the method described in § 1240.4.

§ 1240.4 Test procedure for determining flux index.

(a) Select at least one magnet of each shape and size in the magnet set.

(b) Measure the flux index of each selected magnet in accordance with the procedure in sections 8.24.1 through 8.24.3 of ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, approved on December 1, 2011. The Director of the FEDERAL REGISTER approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box 0700, West Conshohocken, PA 19428; telephone 610-832-9585; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§ 1240.5 Findings.

(a) *Degree and nature of the risk of injury.* (1) Based on a review of National Electronic Injury Surveillance System (NEISS) data, we have determined that an estimated 2,900 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2013, an average of about 580 ingestion incidents per year. From review of databases other than NEISS, we are aware of 109 reported incidents occurring from January 1, 2009 through June 24, 2014, involving the ingestion of magnets by children between the ages of 1 and 15. Of those 109 incidents, 83 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of "magnet set," and 17 of those 109 incidents possibly involved ingestion of this type of magnet. Thus, 100 reported incidents of ingestions in-

volved or possibly involved magnets from magnet sets. Hospitalization was required to treat 61 of the 100 incidents. In 81 of the 100 incidents, the magnets were ingested by children younger than four years old, or between the ages of four and 12 years.

(2) Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly intestinal twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury; but as few as two magnets can cause serious internal damage in a very short time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences to the treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe, as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel transplant; and possible impediments to fertility for girls. Even children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus, exposing children to repeated dosages of radiation.

(b) *Number of consumer products subject to this part.* The market for magnet sets increased substantially from the time magnet sets were first introduced, through mid-2012. We estimate that the number of magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have

totalled about 2.7 million sets, representing a value of roughly \$50 million. Because of CPSC enforcement activity and actions taken by firms since mid-2012, most firms have ceased selling the magnet sets. Actual sales since the end of 2012 by the firms remaining in the market are unknown but believed to be small. The remaining major importing firm that continues to sell the products is estimated to hold a market share of less than 2 percent of pre-enforcement action sales. The approximate number of products subject to this part (in terms of unit sales) could be fewer than 25,000 sets per year.

(c) *The need of the public for magnet sets and the effects of this part on their utility, cost, and availability.* (1) We cannot estimate precisely the use value that consumers receive from magnet sets. In general, use value would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e.*, the difference between the market price and the maximum amount consumers would have been willing to pay for the product). Magnet sets of the type that have been involved in incidents would not comply with this part. Therefore, consumers will no longer be able to obtain utility from these magnet sets. Although magnet sets clearly provide utility to purchasers, magnet sets are not necessities. Products that meet the requirements of this part might be developed that would serve some of the purposes of magnet sets. This part would continue to allow strong magnets for other uses, such as commercial or industrial uses.

(2) Individual magnets that are intended or marketed for use with or as magnet sets also must comply with the requirements of this part. The Commission is aware that firms selling magnet sets have offered individual magnets. To avoid firms circumventing the rule by selling individual magnets that are nevertheless intended or marketed to be used as magnet sets, this part covers such individual magnets. Individual magnets sold for other uses are not subject to this part. Thus, this part does not affect the need for, utility, or availability of individual magnets that are sold for uses other than as magnet sets.

(d) *Other means to achieve the objective of this part, while minimizing the impact on competition and manufacturing.* (1) The Commission considered various alternatives to the requirements specified in this part. This part requires that if a magnet set contains a magnet that fits within the small parts cylinder that CPSC uses for testing toys, all magnets from that set must have a flux index of 50 kG² mm² or less. In addition, individual magnets intended or marketed for use with or as magnet sets must meet these requirements. We do not believe that options other than a rule establishing these requirements would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. The circumstances associated with this product limit the likely effectiveness of warning labels. Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not appreciate the hazard associated with magnet sets. Accordingly, parents and caregivers will continue to allow children access to the product. Children may not appreciate the hazard and will continue to mouth the items, swallow them, or in the case of young adolescents and teens, use the magnets to mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; the small size of the individual magnets precludes the addition of any warning. Because individual magnets from magnet sets are shared easily among children, many end users of the product are likely to have had no exposure to any warning.

(2) The Commission has considered other alternatives to reduce the risk from magnet sets: alternative performance requirements, such as setting a different flux limit or requiring bittering agents; safer packaging requirements, such as requiring a specific design for storage containers or requiring child resistant packaging; sales restrictions; continued corrective actions; and taking no action. Some of these alternatives may not be within the Commission's authority. Although each of the alternative actions would have lower costs and less impact on

small business, none is likely to significantly reduce the injuries associated with ingestion of magnets from magnet sets.

(e) *Unreasonable risk.* (1) As stated in paragraph (a) of this section, according to NEISS, an estimated 2,900 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2013, an average of about 580 ingestion incidents per year. From sources other than NEISS, CPSC has reports of 100 incidents of ingestions that involved or possibly involved magnets from magnet sets, including one fatality.

(2) For the regulatory analysis, we considered the period of time, 2009 through June 2012, before CPSC's compliance activities affected the market. We identified 86 ingestions of high-powered and/or ball-shaped magnets, which occurred from 2009 through June 2012 reported through NEISS. These incidents were determined to involve, or possibly involve, magnet sets. Based on these 86 incidents, we have determined that an estimated 2,138 ingestions of magnets from magnet sets were treated in emergency departments from January 1, 2009 to June 2012. About 11 percent of the victims of these ingestion incidents required hospitalization, as opposed to victims who were treated and released. The 2009 through June 2012 NEISS estimates suggest an estimated annual average of about 610 emergency department-treated injuries, including 544 injuries that were treated and released and 66 injuries that required hospitalization. About 60 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Additionally, based on estimates from the Commission's injury cost model (ICM), there were another 319 injuries treated annually in locations other than hospital emergency departments (such as doctors' offices, clinics, ambulatory surgery centers, or direct hospital admissions).

(3) After including the injuries treated outside of hospital emergency departments, there was an annual average of about 929 medically attended injuries involving ingestions of magnets that were defined as at least "possibly

of interest" during the period from 2009 through June 2012. Injuries resulting from such ingestions of magnets can be severe and life threatening. The risk posed by these magnets may not be appreciated by children or caregivers, who may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets do not pass naturally. Rather, these magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

(4) We estimate that these injuries resulted in annual societal costs of about \$28.6 million (in 2012 dollars) during the 2009 through June 2012 time period. The average estimated societal costs per injury was about \$27,000 for injuries treated in locations other than emergency departments (such as physicians' offices, clinics, ambulatory surgery centers, or direct hospital admissions); about \$21,000 for injuries that were treated and released from emergency departments; and about \$130,000 for injuries that required admission to the hospital for treatment. Preventing these injuries would be the expected benefit resulting from the rule.

(5) The costs of the rule would consist of the lost producer surplus to firms that produce and sell magnet sets, plus the lost use value that consumers would experience when magnet sets that do not comply with the rule are no longer available. Sales of magnet sets averaged roughly 800,000 sets annually during the 2009 through mid-2012 time period, with an average retail price of about \$25 per set in 2012. Thus, total industry revenues averaged about \$20 million annually (*i.e.*, 800,000 sets × \$25 per set) in 2012 dollars. The average import cost of the magnet sets to U.S. importers, a major variable cost, may have amounted to about \$10 per set, or an average of about \$8 million annually (*i.e.*, 800,000 sets × \$10 import cost per set). We estimate other variable costs associated with the production, packaging, marketing, and distribution of the magnet sets would constitute a significant proportion of the remaining difference between revenues (\$20 million) and import costs (\$8 million). If we assume that variable costs amount

to about half of the difference, lost producer surplus would amount to about \$6 million.

(6) Thus, we estimate costs of the rule to be about \$6 million in lost producer surplus and some unknown quantity of lost utility. Considering the injuries associated with magnet sets—and the resulting societal costs, balanced against the likely impact that the rule would have on firms producing and selling the product, and on consumers who would lose the utility of the product—we conclude that magnet sets pose an unreasonable risk of injury and that the rule is reasonably necessary to reduce that risk.

(f) *Public interest.* The regulations in this part are in the public interest because they would reduce deaths and injuries associated with magnet sets in the future. A rule establishing requirements that would eliminate magnet sets of the type that have been involved in incidents will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries.

(g) *Voluntary standards.* Currently, there is no voluntary standard for magnet sets, nor any activity to develop a voluntary standard for magnet sets.

(h) *Relationship of benefits to costs.* (1) Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high-severity injuries that require surgery to remove the magnets and repair internal damage. Based on the information discussed in paragraph (e) of this section, we estimate that the benefits of this part might amount to about \$28.6 million annually.

(2) The costs of the rule, in terms of reduced profits for firms and lost utility by consumers, also are uncertain. However, based on annual sales estimates available for the 2009 through June, 2012, study period, these costs could amount to about \$6 million in lost producer surplus and some unknown quantity of lost utility.

(i) *Least burdensome requirement.* We have considered several alternatives to this part. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative

performance requirements might allow a different flux index for magnets contained in magnetic sets or require the addition of an aversive (bittering) agent to the magnets. Theoretically, these alternatives might allow continued production of some current products. However, it is unclear whether a different flux index would succeed in making products that have the desired physical qualities that make them sufficiently enjoyable to adults, and at the same time eliminate the characteristics that make these strong magnets hazardous to children. Furthermore, the effectiveness of aversive agents in reducing magnet ingestions is questionable. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently and formerly on the market provide warnings concerning the potential hazard to children. Accordingly, it is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings may still not abide by them. Some type of sales restriction, limiting the location where magnet sets could be sold, might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or other locations where adults have brought them and made them available to children. The Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.*, recalls of the product. However, these actions would not prevent additional companies from entering the market and importing magnet sets into the country in the future. The Commission also has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than those resulting from the requirements of this part.

Consumer Product Safety Commission

§ 1301.1

PART 1251—TOYS: DETERMINATIONS REGARDING HEAVY ELEMENTS LIMITS FOR CERTAIN MATERIALS (Eff. 1-19-16)

Sec.

1251.1 The toy standard and testing requirements.

1251.2 Wood.

AUTHORITY: Sec. 3, Pub. L. 110-314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

SOURCE: 80 FR 78656, Dec. 17, 2015, unless otherwise noted.

EFFECTIVE DATE NOTE: At 80 FR 78656, Dec. 17, 2015, part 1251 was added, effective Jan. 19, 2016.

§ 1251.1 The toy standard and testing requirements.

The Consumer Product Safety Improvement Act of 2008 (“CPSIA”) made provisions of ASTM F963, Consumer Product Safety Specifications for Toy Safety (“toy standard”), a mandatory consumer product safety standard. 15 U.S.C. 2056b. The toy standard requires that surface coating materials and accessible substrates of toys that can be sucked, mouthed, or ingested, must comply with solubility limits that the toy standard establishes for eight heavy elements. Materials used in toys subject to the heavy elements limits in the toy standard must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (“CPSA”), unless listed in § 1251.2.

§ 1251.2 Wood.

(a) Unfinished and untreated wood does not exceed the limits for the heavy elements established in the toy standard with a high degree of assurance as that term is defined in 16 CFR part 1107, provided that the material has been neither treated nor adulterated with materials that could result in the addition of any of the heavy elements listed in the toy standard at levels above their respective solubility limits.

(b) For purposes of this section, unfinished and untreated wood means wood harvested from the trunks of trees with no added surface coatings (such as, varnish, paint, shellac, or polyurethane) and no materials added

to the wood substrate (such as, stains, dyes, preservatives, antifungals, or insecticides). Unfinished and untreated wood does not include manufactured or engineered woods (such as pressed wood, plywood, particle board, or fiberboard).

PART 1301—BAN OF UNSTABLE REFUSE BINS

Sec.

1301.1 Scope and application.

1301.2 Purpose.

1301.3 Findings.

1301.4 Definitions.

1301.5 Banning criteria.

1301.6 Test conditions.

1301.7 Test procedures.

1301.8 Effective date.

AUTHORITY: Secs. 8, 9, 86 Stat. 1215-1217, as amended, 90 Stat. 506; 15 U.S.C. 2057, 2058.

SOURCE: 42 FR 30300, June 13, 1977, unless otherwise noted.

§ 1301.1 Scope and application.

(a) In this part 1301 the Consumer Product Safety Commission (Commission) declares that certain unstable refuse bins are banned hazardous products under sections 8 and 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2057 and 2058).

(b) This ban applies to those refuse bins of metal construction that are being distributed in commerce on or after the effective date of this rule, which do not meet the criteria of § 1301.5 and which are produced or distributed for sale to, or for the personal use, consumption or enjoyment of consumers, in or around a permanent or temporary household or residence, a school, in recreation or otherwise. The Commission has found that (1) these refuse bins are being, or will be distributed in commerce; (2) they present an unreasonable risk of injury; and (3) no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with these products. The ban is applicable to those refuse bins having an internal volume one cubic yard or greater by actual measurement, which will tip over when subjected to either of the forces described in § 1301.7 and which are in commerce or being distributed